

COURTNEY M. PRICE
VICE PRESIDENT
CHEMSTAR



June 25, 2001

BY HAND

The Honorable Christine T. Whitman
Administrator, U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

RE: OPPTS-00274D; Voluntary Children's Chemical Evaluation Program
65 Fed. Reg.. 81699 (December 26,2000)

Dear Administrator Whitman:

The American Chemistry Council Ethylbenzene Panel (Panel) volunteers to sponsor ethylbenzene as part of the pilot Voluntary Children's Chemical Evaluation Program (VCCEP). Panel members include ATOFINA Petrochemicals, Inc., BP Amoco Chemical Company, Chevron Phillips Chemical Company, The Dow Chemical Company, GE Plastics, **Lyondell** Chemical Company, NOVA **Chemicals** Inc. and Sterling Chemicals, Inc.

These companies have a long-standing commitment to product stewardship and Responsible Care*. As a result of these and other commitments, Panel member companies have conducted a number of tests and other assessments to better define the potential health effects of ethylbenzene. The Panel member companies' product stewardship activities are designed to promote the safe use of their products and to minimize exposure, including that of children.

A number of the testing components of the VCCEP overlap with testing requirements in the proposed TSCA Test Rule for Hazardous Air Pollutants (HAP). To move forward under both of these programs concurrently, the Panel proposes to conduct those studies that are part of both programs, and to submit the requested Tier 1 assessments to the scientifically-based Peer Consultation upon completion of the testing. As EPA is also aware, the Agency will be updating the IRIS database for ethylbenzene. The completion of this process prior to the development of the VCCEP assessments will ensure the inclusion of up-to-date hazard information in the Tier 1 Peer Consultation process.



Consistent with the requirements of the VCCEP, the Panel commits to the following activities:

- 3 **Testing** – The Panel commits to provide EPA with the results of the following tests, conducted in coordination with other industry test programs:
 - o Reproduction and Fertility Effects (2-generation reproductive toxicity study);
 - o Immunotoxicity;
 - o Prenatal Developmental Toxicity¹; and,
 - o Neurotoxicity Screening Battery.

These studies will complete the ethylbenzene database for Tier 1 and Tier 2, and will complete two of the three requirements for Tier 3 of the VCCEP.

- 3 **Hazard Assessment**-The Panel commits to provide a Tier 1 hazard assessment, which will incorporate the available testing data, the new testing data the Panel herein commits to sponsoring, and the conclusions of the EPA IRIS update. The Hazard Assessment will also incorporate relevant information from the OECD/SIDS assessment (anticipated to be completed mid-2002) and information from the EU Risk Assessment for ethylbenzene.
- **Exposure Assessment** – The Panel commits to provide a Tier 1 Screening Exposure Assessment for ethylbenzene. The Panel will attempt to supplement the Tier 1 screening assessment with more detailed data expected to become available from the Clean Air Act Amendments of 1990 211 (b) exposure study which the American Petroleum Institute is conducting (scheduled to begin in 2001), the OECD/SIDS assessment, and the EU risk assessment.
- **Risk Assessment and Data Needs Assessment**-The Panel commits to provide a Tier I type risk assessment and data needs assessment.

The following table provides the information regarding the sponsored chemical.

¹ The Prenatal Developmental Toxicity endpoint requires testing in two species. Studies have already been conducted in both rats and rabbits. Consequently, the design of additional testing for this endpoint will need to be informed by EPA's review of these existing studies.

Sponsored Chemical for VCCEP Pilot-Tier 1

Chemical	CASRN	Start Date	Submission Date*
Ethylbenzene	100-41-4	12-15-01	01-15-05

* This submission date is the earliest estimated time when all studies (one of which EPA estimates will require 29 months to complete) will have been completed and their results incorporated into the Tier 1 assessments.

In addition, the Panel commits to the other requirements of the VCCEP detailed in the Federal Register, namely to:

- 3 prepare a Peer Consultation Document and provide three hard copies and an electronic copy to EPA;
- make a good faith effort to start and finish all work in a timely manner and within the time period specified;
- 3 make hazard and exposure data developed for this program publicly available through the above-described documents;
- judge existing hazard studies not conducted per Good Laboratory Practices (GLPs) guidelines based on their merits;
- generate any new hazard data using GLPs and current test guidelines as of the date the testing is conducted; and,
- cooperate with other potential ethylbenzene sponsors in performing the tasks described above.

The Panel has a number of questions and concerns pertaining to the exposure information that EPA expects to receive at Tier 1 of the pilot program. Many of these questions we hope will be addressed in the workshops that the Agency intends to sponsor. Based on comments made by Mr. Steve Johnson to the American Chemistry Council on May 11, 2001, and in Mr. Johnson's letter of June 22, 2001 to Ms. Sandra Tirey of the American Chemistry Council, it is the Panel's understanding that EPA does not expect Class 1 producers to submit exposure data pertaining to activities that are outside their control, beyond readily available public information for Tier 1. The activities that are outside the control of the Ethylbenzene Panel include ethylbenzene as a component of hydrocarbon solvents, as a component of fuels, and as a result of combustion. The Panel will, however, seek the cooperation of Class 2 producers on exposure issues, and would certainly welcome their participation in the pilot program.

In conclusion, the Ethylbenzene Panel hereby makes a voluntary commitment to develop hazard and exposure data on ethylbenzene consistent with the requirements of

the VCCEP pilot program. The Panel also understands that because this voluntary commitment includes conducting studies proposed for the HAP Test Rule, any future version of the HAP Test Rule will acknowledge that the Panel has already committed to completing these studies.

The technical contact for this activity is:

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Please contact Ms. Messenger if you have any questions regarding this commitment.

Sincerely yours,

Courtney M. Price
Vice-President, CHEMSTAR

cc: OPPT Document Control Office
Mr. Stephen L. Johnson, US EPA OPPT
Mr. William H. Sanders, US EPA OPPT
Ms. Mary Ellen Weber, US EPA OPPT
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Ethylbenzene Panel